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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,497	07/06/2001	Keith D. Allen	R-639	4128

7590 06/03/2003
DELTAGEN, INC.
1003 Hamilton Avenue
Menlo Park, CA 94025

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/03/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,497

Applicant(s)

ALLEN, KEITH D.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 16 and 20-30 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 12, 16, 20-30 are pending in the application.

Claims 16 and 20 are withdrawn from consideration for being directed to non-elected subject matter. Claims 12 and 21-30 are currently under examination.

This Office Action is in response to the Amendment filed on 3/17/03.

Response to Amendment

The objection to claim 2 is moot in light of Applicant's cancellation of the claim.

The rejection of claims 5-15 and 17-19 under 35 U.S.C. 112 first paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claims 1-4, 9 and 10 under 35 U.S.C. 112 second paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claims 1-10 under 35 U.S.C. 103 (a) is moot in light of Applicant's cancellation of the claims.

Claim 12 and newly added claims 21-30 are rejected under 35 U.S.C. 112 1st paragraph for reasons discussed below.

Newly added claim 24 is rejected under 35 U.S.C. 112 1st paragraph for reasons set forth of the record mailed on 9/9/02 and further discussed below.

Newly added claims 26-30 are rejected under 35 U.S.C. 103 (a) for reasons set forth of the record and further discussed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 21-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 12, 21-30 recite that the transgenic mouse exhibits a neuromuscular phenotype. The specification only discloses that the transgenic mouse exhibits increased agility and coordination. The limitation of "neuromuscular phenotype" is not supported by the instant specification and therefore constitutes new matter.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Newly added claim 24 is rejected for same reasons as applied to now cancelled claims 5-10 and 17-19 that were set forth in the office action mailed on 9/9/02 (see pages 3-9).

The nature of the invention is a cell isolated from a transgenic mouse having a disruption of NPY6 receptor gene, wherein when the disruption is homozygous, it exhibits the phenotype of increased agility or coordination. The specification teaches that the cell isolated from the transgenic mouse can be used in assays to screen for agents that ameliorate a phenotype of the transgenic mouse. However, the disclosed phenotype of the homozygous transgenic NPY6

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knockout mouse is increased agility or coordination, which can only be determined by a mouse. A cell in culture, isolated from the transgenic mouse would not exhibit this phenotype. The specification fails to teach how to use a cell isolated from said transgenic mouse to screen for an agent that ameliorates a phenotype of the transgenic mouse. As such, whether a cell isolated from the claimed transgenic mouse can be used to screen for agents that ameliorate a phenotype of said mouse is unpredictable. Thus, the specification, in the instant case, is not enabling for a cell isolated from the transgenic knockout mouse for the screening of agents that ameliorate a phenotype of said mouse. One skilled in the art would have to engage in undue amount of experimentation to use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansour et al (1988, Nature, vol. 336, No. 24, 348-352), in view of Weinberg et al. (1996, JBC Vol. 271, pages 16435-16438).

The teaching of Mansour et al. and Weinberg et al. were discussed in the Office Action mailed on 9/9/02 (paper no.12).

In response to Applicant's argument that the combined teachings of the references do not meet every limitation of the claims, Applicant is reminded that the recitation of "wherein the

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targeting vector, when introduced into a murine embryonic stem cell...the mouse exhibits a neuromuscular phenotype..." merely defines the intended use of the knockout construct, which does not carry patentable weight.

In response to Applicant's argument that there is insufficient motivation to combine the references and make the claimed NPY6 receptor knockout constructs and a NPY6 knockout mouse, Applicant is reminded that suggestion or motivation to combine references does not need to be explicitly in the references cited but rather may be based on common knowledge in the art (MPEP 2144.03). The ordinary artisan would have been motivated to knockout the expression of the NPY6 receptor gene in a cell or a mouse to study the role it plays in the complex biology of NPY and determine which NPY signaling pathway(s) it mediates, as suggested by the teaching of Weinberg et al. Weinberg et al. teach that inhibiting said receptor by antisense or antibody would help to address the precise physiological role of this receptor. Although Weinberg et al. do not teach generation of a NPY6 knockout mouse, it is common knowledge that gene knockout in a mouse model is a well-known tool to study a specific gene function *in vivo* (for example, see Mansour et al., page 349, 1st col., 1st paragraph). The ordinary artisan would have had reasonable expectation of success for making such a knockout mouse because of the teaching of Mansour et al., who teach a general method of targeted gene disruption in murine embryonic stem cells based on homologous recombination using a cloned fragment of a desired gene. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

This application contains claims 16 and 20 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

May 30, 2003



REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600